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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,539	06/06/2001	Victor C.W. Tsang	14114.0358U2	6357

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EXAMINER

NGUYEN, BAO THUY L

ART UNIT PAPER NUMBER

1641

DATE MAILED: 09/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/857,539	Applicant(s) TSANG ET AL.	
	Examiner Bao-Thuy L. Nguyen	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 6-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 17 and 18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. Applicant's amendment filed 09 June 2004 has been received. Claims 1-18 are pending. Claims 6-16 have been withdrawn.
2. All rejections not reiterated herein below are withdrawn.
3. The text of those US codes not found in this office action may be found in a previous office action.

#### *Claim Rejections - 35 USC § 102*

4. Claims 1-4, 17 and 18 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Farrington et al., *Veterinary Parasitology*. 1995. Vol. 60, No. 1-2, pp. 7-16 for reasons of record which is reiterated herein below.

Farrington discloses a method for detecting soluble antigen using monoclonal antibody against *C. Parvum* oocysts. See page 9.

5. Claims 1, 3, 4, 17 and 18 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Moss et al., *Am. J. Trop. Med. Hyg.* Vol. 49, No. 3, 1993, pp. 393-401 for reasons of record which is reiterated herein below.

Moss discloses rabbit antiserum against soluble proteins from *C. Parvum* oocysts. See pages 394, 396 and lane D of Figure 2.

6. Claims 1-4, 17 and 18 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Perryman et al (WO 98/07320) for reasons of record which is reiterated herein below.

Perryman discloses antibodies specific to *c. parvum* sporozoites. See pages 13 and 14.

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7. Claims 1-4, 17 and 18 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Petersen et al., *Infection and Immunity*. 1992. Vol. 60, No. 12, pp. 5132-5138 for reasons of record which is reiterated herein below.

Petersen discloses monoclonal antibodies to a soluble *C. parvum* sporozoite glycoprotein. See pages 5133-5137.

8. Claims 1-4, 17 and 18 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Riggs et al (WO 97/36612) for reasons of record which is reiterated herein below.

Riggs discloses compositions comprising monoclonal antibodies to *C. parvum* sporozoite. See pages 4-6.

9. Claims 1-4, 17 and 18 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Tilley et al., *FEMS Microbiology Letters*. 1993. Vol. 113, No. 2, pp. 235-240 for reasons of record which is reiterated herein below.

Tilley discloses monoclonal antibodies that bind sporozoite surface and apical complex antigens. See pages 236, 273 and Table 1.

### ***Response to Arguments***

10. Applicant's arguments filed 09 June 2004 have been fully considered but they are not persuasive.

Applicant argues that Farrington does not teach an antibody specific for *C. parvum* because the antibody of Farrington is described as a *Cryptosporidium* oocyst monoclonal antibody and not just as a *C. parvum* antibody. Applicant also argues that since Farrington

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states that the antigens to which the antibody binds, is soluble or finely particulate antigen, Farrington does not teach an antibody specific for a soluble antigen.

These arguments are not persuasive. Farrington specifically discloses a monoclonal antibody able to detect soluble antigens from *Cryptosporidium parvum*. See Abstract, page 9 and page 14. There is no discussion of any other *Cryptosporidium* species in this reference, therefore, the argument that the *Cryptosporidium* monoclonal antibody cannot be the same as a *C. parvum* antibody is not persuasive.

The argument that the antibody of Farrington is not specific for a soluble antigen because it binds both soluble and finely particulate antigens is not persuasive. Farrington clearly discloses an antibody that binds to soluble *C. parvum* antigens as discussed through the reference. Furthermore, the specification does not specifically define "specific for". The specification at page 9, lines 11-14 and page 10, lines 19-23 states that an antibody to *C. parvum* that is specific for viable *C. parvum* oocysts and does not cross react with other *Cryptosporidium* species or other parasites is disclosed. Therefore, the antibody of Farrington meets this limitation.

With respect to the Moss reference, applicant argues that even though Moss discloses soluble antigens and antibodies directed therefor, Moss does not teach that the antibodies are *specific* for soluble the soluble antigens. Applicant argues that because Moss teaches antibodies that recognized both soluble proteins and insoluble proteins, the antibodies of Moss are not specific for soluble antigen. Applicant further argues that the monoclonal antibody C8C5 disclosed by Moss is specific for the 23-kD antigen found on the surface of sporozoites and is therefore not a soluble antigen.

These arguments are not persuasive. The discussion of the term “specific” can be found above. In sum, since this term lacks a specific definition in the specification, and the claimed antibody is described as specific for viable *C. parvum* oocysts and does not cross-react with other *Cryptosporidium* species or other parasites, such an antibody is disclosed by Moss.

The argument that the 23-kD antigen found on the surface of sporozoites is not soluble and thus the antibody disclosed by Moss is not specific for a soluble antigen is not persuasive. Nowhere in Moss is there a recitation of the 23-kD antigen not being a soluble antigen. Moss specifically teaches an antibody that binds to soluble antigens from *C. parvum*. Furthermore, the specification at page 13, lines 5-16 discloses an antibody having binding specificity for a soluble *C. parvum* sporozoite antigen. The antibody is described as being specific for an antigen, such as a membrane-bound protein or glycoprotein, and as being specific for *C. parvum* and exhibits minimal or no cross reactive binding to other *Cryptosporidium* species. Therefore, the antibody disclosed by Moss meets these limitations.

The argument directed to the lymphocytes assays described by Moss is not on point since this discussion does not take away from the fact that the antibodies disclosed by Moss binds to soluble antigens from *C. parvum* sporozoite.

With respect to the Perryman reference, Applicant argues that the antibodies of Perryman are not specific for a soluble antigen because they bind to epitopes within a surface glycoprotein and since Perryman does not teach that glycoprotein is soluble, the disclosed antibodies are not specific for a soluble antigen.

These arguments are not persuasive. Perryman discloses, on page 13, the process of preparing antigens from sporozoites by solubilizing them in the presence of protease inhibitors and on page 14, antibodies binding to sporozoites antigens. Therefore, Perryman is seen to

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disclose antibodies binding to soluble sporozoites antigens. The discussion of the surface glycoprotein is not persuasive since the instant specification teaches antibody to membrane-bound protein or glycoprotein. Absent evidence to the contrary, the membrane bound protein or glycoprotein discussed by the instant specification is seen to be the same as those disclosed by Perryman and any antibody binding thereto must inherently be the same.

With respect to the Petersen reference, Applicant argues the Petersen does not disclose that the antigen is soluble under normal cellular conditions. Instead, Petersen teaches that the antigen is Triton X-100 soluble. Therefore, Petersen does not teach an antibody specific for a soluble antigen of *C. parvum* sporozoite. Applicant also argues that because the monoclonal antibodies taught by Petersen cross-react with other antigens, they cannot be considered specific for a sporozoite antigen.

These arguments are not persuasive. Since “soluble” is defined in the specification as partially or completely dissolved in an aqueous solution, such a definition does not limit it to an antigen soluble under normal cellular conditions as argued. Instead, an antigen shown to be Triton X-100 soluble (e.g. the 900,000-M<sub>r</sub> protein) falls within this definition. As discussed above, because the term “specific for” has not been specifically defined in the specification, and because the specification at page 9, lines 11-14 and page 10, lines 19-23 teaches that the instantly claimed antibody is an antibody to *C. parvum* that is specific for viable *C. parvum* oocysts and does not cross react with other *Cryptosporidium* species or other parasites, such an antibody is disclosed by Petersen.

The argument that the monoclonal antibody designated E6 is disclosed by the Fukumoto reference, (Exhibit B), as reactive with *Babesia gibsoni* merozoites and is therefore not specific for *C. parvum* sporozoites is not persuasive. The Mab E6 disclosed by Petersen specifically binds to

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a *C. parvum* sporozoites soluble antigen and is not disclosed as having any cross reactivity with any other species of *Cryptosporidium* or any other parasites. Conventionally, monoclonal antibodies are given a laboratory designation and/or a name related to their antigen. For example Mab E6 is most likely a conventional laboratory designation to indicate that the monoclonal antibody was from row E, column 6 of a 96-well microtiter plate. As such, a number of different laboratories working on entirely different subject matter could theoretically produce monoclonal antibodies that have the same designation, i.e. E6, but are in no way related. Such is the case with the Fukumoto reference. Since the monoclonal antibody designated E6 of the Fukumoto reference is made using an antigen from an entirely different parasite, *Babesia gibsoni*, and the reference does not contain any information that would lead one to think that this parasite is in anyway related to *C. parvum*, nor does the reference state that the monoclonal antibody designated E6 was obtained from the same commercial and/or laboratory sources as that disclosed by Petersen, it can only be concluded that the antibody E6 of Fukumoto is not the same as the antibody E6 of Petersen. Therefore, the argument that the Mab E6 of Petersen has been shown to have a cross reactivity with another parasite is not persuasive.

Furthermore, the claims are not limited to an antibody to *C. parvum* sporozoite that does not cross-react with other *C. parvum* antigens, only that it does not cross-react with other *Cryptosporidium* species and/or parasites. Specifically, the claimed antibody is disclosed as being specific for an antigen, such as a membrane-bound protein or glycoprotein. The antibody is specific for *C. parvum* and exhibits minimal or no cross-reactive binding to other *Cryptosporidium* species (page 13 of the specification).



With respect to the Riggs reference, Applicant argues that Riggs does not teach antibodies specific to a soluble antigen of *C. parvum* because the antibodies taught by Riggs also binds to oocyst walls.

This argument has been fully considered but is not persuasive. Riggs discloses on pages 5 and 6, example 1, solubilized sporozoite and antibodies binding therefor. The fact that some of the antibodies disclosed by Riggs have cross reactivity with oocyst walls is not relevant since the claims do not exclude such a possibility.

With respect to the Tilley reference, Applicant argues that Tilley does not teach antibodies specific for soluble antigen of *C. parvum* because the antibodies of Tilley binds to sporozoite surface, apical surface and inner oocyst wall and thus, are not soluble by definition. Applicant also argues that these antibodies were shown to have cross reactivity with sporozoite and merozoite surface and are therefore not sporozoite specific.

This argument is not persuasive because, as argued previously, the claims are not limited to antibodies that do not have any cross-reactivity and since the antibodies disclosed by Tilley as being able to bind to soluble antigen of *C. parvum* sporozoite, they anticipate the claims.

***Allowable Subject Matter***

**11.** Claim 5 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

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**12.** The following is a statement of reasons for the indication of allowable subject matter: the prior art of record fails to disclose the monoclonal antibody having ATCC designation CRL-12604.

*Conclusion*

**13. THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

**14.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Thursday from 8:00 a.m. -3:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Bao-Thuy L. Nguyen  
Primary Examiner  
Art Unit 1641  
9/8/04